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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,025

11/21/2003

Elliot Lorne Chaikof

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GREENLEE WINNER AND SULLIVAN P C

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SUITE 200

BOULDER, CO 80301

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

01/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,025	Applicant(s) CHAIKOF ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-76 is/are pending in the application.
- 4a) Of the above claim(s) 12-32,35,36 and 41-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-11,33,34 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The amendments to the claims and response to the previous Office action (a Non-Final Office action) are acknowledged. Claims 1, 3-6 and 8-76 are pending; claims 12-32, 36, 36 and 41-76 remain withdrawn from consideration for the reasons recited in the previous Office action. Claims 1, 2-6, 8-11, 33, 34 and 37-40 are subject to Examination on the merits.

Withdrawal of Previous Rejections/Objections

2. Any objection/rejection previously recited and not reiterated below is hereby withdrawn.

3. The rejection of claims 1, 3-5, 8-11, 33, 34 and 37-40 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to claim 1.

4. The rejection of claims 1, 3, 5, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright et al. (Adv. Funct. Materials, Feb. 2002, 12:149-54 – cited on IDS of 1/21/04) is withdrawn as said reference does not teach wherein the first or second end block is SEQ ID NO: 11 or 12; rather the first and second end block are taught as: {(VPAVG)(IPAVG)₄(VPAVG)₁₆IPAVG} which is not necessarily encompassed within [VPAVG(IPAVG)₄]_n e.g. (SEQ ID NO: 11) or [(IPAVG)₄(VPAVG)]_n e.g. SEQ ID NO: 12.

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5. The rejection of claims 1, 3, 11, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al. (Macromolecules, 1999, 32:241-44) is withdrawn in view of the amendments to claim 1.

Maintained Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 3-5, 8-11, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright and Conticello (Adv. Drug Deliv. Rev., Oct. 2002, 54:1057-73 – cited on IDS from 1/21/04).

The claims are drawn to synthetic protein copolymers of the construction BAB wherein the A block is selected from a hydrophilic middle block: SEQ ID NO: 21, 23, 24, 25, 30, 33, 35, 38, 41, 42, 43, (SEQ ID NO: 63)_m, (SEQ ID NO: 14)_m, (SEQ ID NO: 15)_m, (SEQ ID NO: 18)_m, with m being about 10 to 100 and B is a hydrophobic block of SEQ ID NO: 11 or 12

Wright and Conticello teach synthetic protein copolymers of the construction AB and BAB, wherein A is a hydrophilic block and B is a hydrophobic block. Various representative B and A blocks are taught in Table 2, p. 1060. It is noted that the B blocks are of the form: [VPAVG(IPAVG)₄]₁₆ which is encompassed in the instant SEQ ID

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NO: 11 - [VPAVG(IPAVG)₄]_n. Also, taught for the A or middle block, are the instant SEQ ID NOs: 14 and 15 which are respectively encompassed by copolymer A of Polymer# 4 (SEQ ID NO: 14 and 15) and expressly taught is copolymer A from Polymer #'s 3-7 which are the instant SEQ ID Nos: 38, 41, 42, 43 and 63 (see Table 2). The copolymers form microparticles (e.g. self-assembled gels – see Figure 7) and also have inverse transition temperatures at about 25°C (see p. 1068, 1st column, 1st paragraph).

Response to Declarations

8. The declarations filed under 37 CFR 1.131 on 06 November 2009 are insufficient to overcome the rejection of claims 1, 3-5, 8-11, 33, 34 and 37-40, rejected under 35 U.S.C. 102(a) as being anticipated by (a) Wright and Conticello (Adv. Drug Deliv. Rev., Oct. 2002, 54:1057-73 – cited on IDS from 1/21/04) and the rejection of claims 1-3, 5, 33, 34 and 37-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Wright et al. (Adv. Funct. Materials, Feb. 2002, 12:149-54 – cited on IDS of 1/21/04) as set forth in the last Office action because of the following deficiencies:

(a) The instant application lists seven different inventors, Chaikof, Nagapudi, Brinkman, Conticello, McMillan, Wright and Payne. However, the declaration is only signed by a single inventor, Conticello, rather than **all** of the inventors as required.

(b) As noted in (a), the application lists seven inventors, however, only one of the seven inventors (Conticello) is listed as attesting to the facts and statements of the declaration. **All** seven inventors need to attest to the statements of fact in said declaration (and sign as noted in (a)).

c) The declaration is attempting to establish a reduction to practice before the date of the two references, however, it is necessary to establish in which country the reduction to practice occurred – see 37 CFR 1.131(a).

(d) In establishing the reduction to practice before the date of the two references it is necessary to establish the date with the showing of facts which are “such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained.” – see 37 CFR 1.131(b) and MPEP 715.

Thus, simply relying upon the fact that the reference itself, which is being used as the 102(a) reference, was submitted and/or accepted prior to the publication date is insufficient. Rather, what is required is, for example, lab notes with the noted sequences which have a date which antedates the publication dates of the 102(a) references or any other kind of document, email, etc. which clearly indicates the conception and reduction to practice of the noted sequences/invention and which clearly has a date which antedates the noted references.

Response to Arguments

9. Applicant's arguments filed 06 November 2009 have been fully considered but they are not persuasive.

Applicants arguments regarding the 35 U.S.C. 102(a) rejections of record have been considered but are unpersuasive to overcome the rejections of record for the reasons set forth above in the response to Applicants Declarations filed under 37 C.F.R. 1.131.

All other rejections of record have been withdrawn due to the amendments to the claims.

Conclusion

10. No claim is allowed. Applicants are encouraged to call the undersigned Examiner with any queries.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
04 January 2010